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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,531	09/05/2003	David Baltimore	CTCH-P01-016	8769
28120	7590	05/19/2005	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			PATTERSON, CHARLES L JR	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/656,531

Applicant(s)

BALTIMORE ET AL.

Examiner

Charles L. Patterson, Jr.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 2/17/04, 1/27/05 & 4/14/05.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13,18,20,21,28,40,43 and 98-123 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13,18,20,21,28,40,43 and 98-123 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Applicant's election with traverse of Group IV, claims 21, 28, 40 and 43 in the reply filed on 4/4/05 is acknowledged. The traversal is on the grounds that there is no significant burden in examining Group I and IV because the two groups have overlapping subject matter, searches for the two groups would be co-extensive and they are both classified in Group 435. This is not found persuasive because Group I is simply drawn to a chimeric nuclease and nucleic acid encoding it that has (1) a DNA binding domain, (2) a cleavage domain and (3) a nuclear localization signal, while Group IV is drawn to a vector, a cell containing the vector and a method of use, the vector containing a nucleic acid encoding a chimeric nuclease with a cleavage and binding domain and additional a nucleic acid comprising a repair substrate. The repair substrate does not appear in Group I and is not involved in the use of Group I. Group I would read on any chimeric enzyme with these characteristics and would involve different 35 USC § 112 in addition to any prior art issues than Group IV. Group IV is drawn to the use of a repair substrate to change a particular DNA sequence whereas Group I is not. The fact that both are classified in Group 435 has no bearing as this group contains all of molecular biology and microbiology, a wide variation of subject matter. However, after reading the instant specification and because the examiner is required to search Group I in the corresponding PCT application, the examiner will examine all pending claims, i.e. 1-13, 18, 20-21, 28, 40, 43 and 98-123. The requirement is still deemed proper and is therefore made FINAL.

The disclosure is objected to because of the following informalities:

On page 16, line 15 and page 53, lines 3-4, the recitation of "in red" is not understood. The instant figure does not have any colors.

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Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 12-13, 18 and 20 are rejected under 35 U.S.C. 102(a or b) as being anticipated by either of Bibikova, et al. (CA), Chandrasegaran, et al. (CE), Kim, et al. (CU, CT1) or Smith, et al. (CL1, CM1). The instant references teach a chimeric nuclease that it is maintained meets the requirements of the instant claims, absent very convincing proof to the contrary. The requirement of claims 8 and 18 of recognition sequence within 500 base pairs of the allele for a genetic disorder is all but impossible to determine because it is a very broad term and all such alleles related to genetic disorders have not been determined. It is maintained that this requirement is inherent, absent convincing proof to the contrary.

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Claims 1-13, 18, 20-21, 28, 40, 43 and 98-123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bibikova, et al. (CA). Bibikova, et al. teach the use of a chimeric nuclease consisting of the cleavage domain of *FokI* and a DNA binding domain consisting of zinc fingers. In the sentence spanning pages 289-290 it is stated that "randomization of the codons for the recognition residues allows the selection of new fingers that have high affinity for arbitrarily chosen DNA sequences", and in the next paragraph it is stated that "[i]njected linear DNAs undergo efficient recombination if they carry appropriately placed homologous sequences". In the last full paragraph of column 1 on page 296 it is stated that "two new chimeric nucleases would be delivered to cells along with a linear donor DNA molecule carrying the desired sequence alteration [and that] [t]he method of delivery would depend on the organism, cell type, and other experimental conditions". It is maintained that it would have been obvious to one of ordinary skill in the art to produce all of the elements of the instant claims either in view of the instant reference alone or also in view of widely known and used procedures such as insertion of DNA into a vector and/or into a cell, absent very convincing proof to the contrary. It is further maintained that the chimeric enzyme contains a nuclear localization signal or it would have been obvious to add it. This nuclear localization signal is defined in the paragraph spanning pages 22-23 as "one...or two... clusters of four or more basic amino acids". The use of a recognition sequence within 500 base pairs of the allele for a genetic disorder would have been obvious with the motivation being to see if the gene change affected that disease, but it is all but impossible to determine if the recognition sequence is within 500 base pairs because "a genetic disorder" is a very broad term and all such alleles have not been determined.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.  
Primary Examiner  
Art Unit 1652

Patterson  
May 16, 2005